PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Group Art Unit: 1632

Examiner: Anne Marie Sabrina Wehbe

In re application of:
Alain P. Vicari *et al.*

Serial No.: 09/768,917

Filing Date: January 24, 2001

Attorney Docket No.: SF0896 K US

Title:
CHEMOKINES AS ADJUVANTS OF IMMUNE RESPONSE

DECLARATION UNDER 37 C.F.R. § 1.131

We, the undersigned, Alain P. Vicari and Christophe Caux, each hereby declare as follows:

1. I am a named inventor in the above-referenced patent application. I am informed that the claims in the above-referenced patent application have been amended to recite a method for enhancing a humoral immune response in a mammal comprising administering an antigen and a chemokine to the mammal, wherein the chemokine is MCP-4 or a biologically active fraction of MCP-4, and wherein the antigen and the chemokine are not physically linked as a fusion protein

2. Furthermore, I am informed that Schering-Plough Corporation received an Office Action having a mailing date of April 16, 2004 in the above-referenced application. I have also been informed that the Office Action rejects claims 21-24, 27, 29, 31, 33, 35-36 and 69 under 35 U.S.C. § 102(e) as being anticipated by United States Patent Application Publication No. 2002/0071825 ("Schall").

3. At all times relevant to the activities described herein, I was employed by the Laboratory for Immunological Research of Schering-Plough (France), a subsidiary of Schering-Plough Corporation, and all of the work referenced to in this declaration was performed either by myself or under my direction at that location.

4. I hereby declare that on a date prior to April 21, 2000, I performed experiments in my laboratory that compared MCP-4 and MIP-3α's ability to generate an antigen-specific humoral response following beta-galactosidase immunization. Briefly, mice were injected with either 50 μl PBS or 50 μl chemokine (MIP-3α or MCP-4) diluted in PBS (= 100ng). After 3 hours, the mice were injected with 50 μg (50 μl) of either pLacZ or control plasmid pcDNA3. Injections were performed on days 0, 7, 14 and 21. Blood sampling for serum was performed on days 0, 14 and 28. The results show that hMCP-4 injection increases the antigen specific humoral response following immunization, whereas hMIP-3α injection does not.

5. I recorded the above experiments and resultant data into my laboratory notebook, which is identified as 99-06-03. Attached hereto as "Exhibit A" (5 pages) is a true photocopy of the relevant pages from that notebook, pages 164, 165, 166, 167 and 168, altered only by obliterating all dates appearing thereon. Each of pages 164-168 was signed by Alain P. Vicari prior to April 20, 2000 and was also witnessed by another co-worker on a date prior to April 20, 2000.

6. The above laboratory notebook entries are in the French language. Therefore, I have translated the relevant portions of the text on pages 164-168 of the notebook into the English language. Attached hereto as "Exhibit B" (2 pages) is the English language translation. The translated text that is in *italics* is not part of the original text in the laboratory notebook. The text in *italics* either describes the data sets or indicates where irrelevant experiments appear. I hereby declare that I am knowledgeable in both the English and French languages, and that I believe the English translation of the text of the above laboratory notebook pages is a true and complete translation.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statement were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment or both under 18 U.S.C. § 1001 and that such willful false statement may jeopardize the validity of the application and any patent issued thereon.

Alain P. Vicari

August 12, 2004
Date

Christophe Caux

August 11, 2004
Date